

Symposium on the identification of substances in medical products.

An opportunity to discuss current challenges with participants & experts in sciences supporting the ISO 11238 standard.

September 7-8, 2015

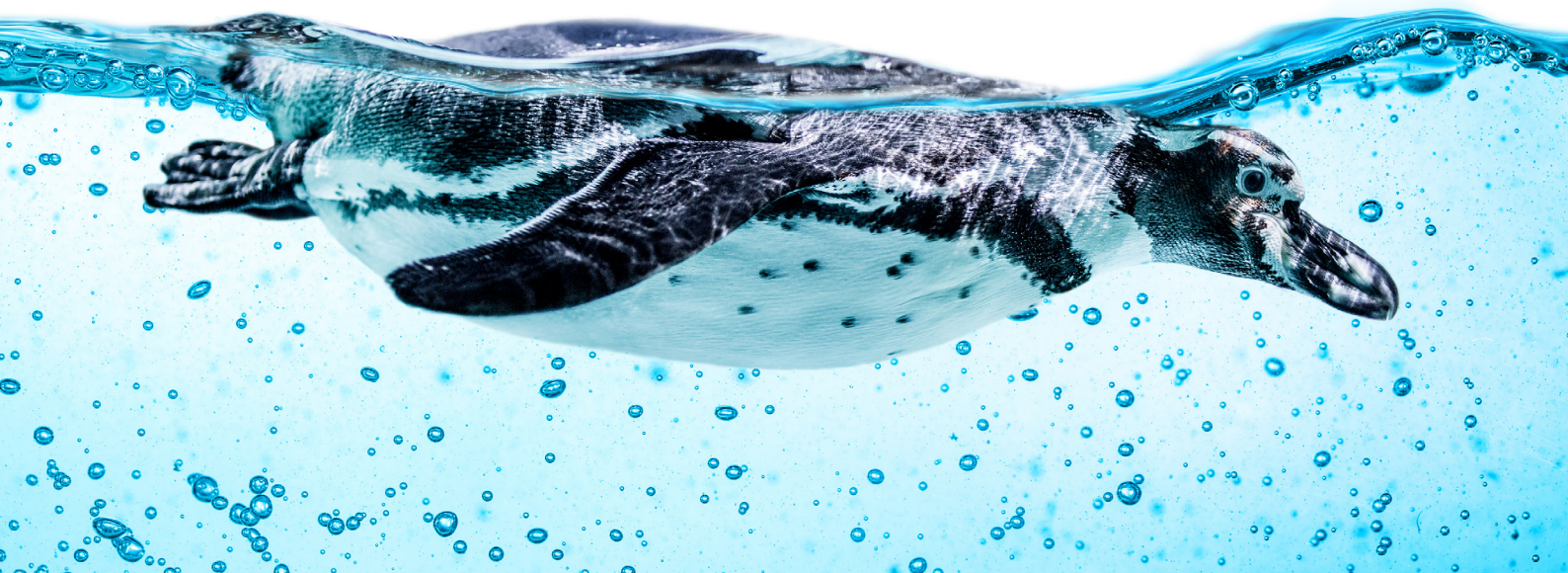


Uppsala, Sweden

Uppsala Monitoring Centre (UMC) and the National Center for Advancing Translational Sciences at the National Institutes of Health (NIH/NCATS) are hosting a two-day meeting on the **ginas** initiative and its G-SRS software on Monday, September 7 and Tuesday, September 8, 2015 at Clarion Hotel Gillet in Uppsala, Sweden.

This meeting will address both scientific and information technology aspects of defining, registering and linking essential information related to substances in medicinal products.

The growing impact of globalization presents tremendous challenges and opportunities for national regulatory agencies, the pharmaceutical industry, and global health as a whole. Ingredients for pharmaceutical products are sourced on a global basis and it is essential to have a global information system for pharmaceutical ingredients.



PROGRAM MONDAY

Hosted by Uppsala Monitoring Centre, Clarion Hotel Gillet, Dragarbrunnsgatan 23, 753 20 Uppsala

Monday, September 7

Opportunities for a global identifier of substances in medical products

Chair: Malin Jakobsson, Uppsala Monitoring Centre

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| 08:30-08:45 | Introduction and Welcome
Marie Lindquist, Uppsala Monitoring Centre |
| 08:45-09:15 | Overview of the ginas project
Noel Southall, Informatics National Center for Advancing Translational Sciences,
National Institutes of Health |
| 09:15-09:45 | Substance identifiers in regulatory practice
Frank Switzer, US Food & Drug Administration |
| 09:45-10:15 | Substance identifiers to organize scientific data
Larry Callahan, US Food & Drug Administration |
| 10:15-10:30 | Break |
| 10:30-11:30 | Use of substance information at UMC and WHO programme for International Drug
Monitoring
Sten Olsson, Tomas Bergvall, Malin Jakobsson, Uppsala Monitoring Centre |
| 11:30-12:00 | Allotrope initiative
Gerhard Noelken, Pfizer |
| 12:00-12:30 | G-SRS software for substance registration
Tyler Peryea, National Center for Advancing Translational Sciences,
National Institutes of Health |
| 12:30-13:30 | Lunch |
| Chair: Frank Switzer, US Food & Drug Administration | |
| 13:30-14:00 | Status of ISO 11238 in Europe
Paolo Alcini, European Medicines Agency |
| 14:00-14:30 | Status of ISO 11238 at FDA
Vada Perkins, US Food & Drug Administration |
| 14:30-15:00 | Astellas Preparations Toward IDMP Compliant Substance Management
Frits Stulp, Astellas Pharma |
| 15:00-15:30 | Break |
| 15:30-16:00 | Pharmacopeias substances
Hans-Joachim Bigalke, European Directorate for the Quality of Medicines |
| 16:00-16:30 | Pharmacopeias substances
Fouad Atouf and Tina Morris, U.S. Pharmacopeial Convention |
| 16:30-17:00 | State of public seed data and system demo
Tyler Peryea, National Center for Advancing Translational Sciences,
National Institutes of Health |
| 18:00-19:00 | Reception at Uppsala Monitoring Centre, Bredgränd 7 |

PROGRAM TUESDAY

Tuesday, September 8

Planning for a global identifier of substances in medical products

Chair: Herman Diederik, College ter Beoordeling van Geneesmiddelen

09:00-09:30	Substance Levels Relation to Products Herman Diederik, College ter Beoordeling van Geneesmiddelen
09:30-10:00	Substances Definitions in the Clinical Trial Registry Standards Paul Houston, Clinical Data Interchange Standards Consortium
10:00-10:30	Controlled Vocabulary in ginas Thomas Balzer, Bundesinstitut für Arzneimittel und Medizinprodukte
10:30-11:00	Break
11:00-11:30	Subject Matter Expert Topic: Identification of Plants in Commerce Bob Allkin, Royal Botanic Gardens, Kew
11:30-12:00	G-SRS Software Development Tim Sheils, National Center for Advancing Translational Sciences, National Institutes of Health
12:00-14:00	Lunch, Q&A and demos/ birds of a feather (software, extensibility, data model, registration)
14:00-14:30	Subject Matter Expert Topic: Blood products and cell therapies Larry Callahan, US Food & Drug Administration
14:30-15:00	Subject Matter Expert Topic: Vaccines Frank Switzer, US Food & Drug Administration
15:00-15:30	Subject Matter Expert Topic: Advanced Therapeutic Medicinal Products Marcel Hoefnagel, College ter Beoordeling van Geneesmiddelen
15:30-16:00	Break
16:00-17:00	ginas collaboration, development roadmap, and next steps Tyler Peryea, National Center for Advancing Translational Sciences, National Institutes of Health

The Global Ingredient Archival System (**ginas**) represents a major opportunity for international efforts to tackle these challenges. This tool will make it possible to create a global standard for defining substances and a common identifier to identify ingredients in medicinal products. This will enable the global health community to share and use information to significantly improve healthcare delivery, the proper use of medications, and the management of risks involved in their use.

About Uppsala Monitoring Centre:

Uppsala Monitoring Centre advances the science of pharmacovigilance and inspires patient safety initiatives all over the world. As an independent, non-profit foundation, we engage stakeholders who share our vision and collaborate to build a global patient safety culture. As a leader in the research and development of new scientific methods, we explore the benefits and risks of medicines to help minimize harm to patients, and offer products and services used by health authorities and life-science companies worldwide. Our unique expertise makes us an organisation with the capacity to transform patient safety from an ambition into a reality. For almost 40 years, we have provided scientific leadership and operational support to the WHO Programme for International Drug Monitoring, expanding the global pharmacovigilance network to reach more than 95% of the world's population.

INSPIRE. ENGAGE. TRANSFORM.



For further information or for assistance with planning your attendance please contact Uppsala Monitoring Centre on:

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